Complete Summary

GUIDELINE TITLE

Practice guideline for the performance of total body irradiation.

BIBLIOGRAPHIC SOURCE(S)

American College of Radiology (ACR). ACR practice guideline for the performance of total body irradiation. Reston (VA): American College of Radiology (ACR); 2006. 5 p. [6 references]

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

SCOPE

METHODOLOGY - including Rating Scheme and Cost Analysis
RECOMMENDATIONS
EVIDENCE SUPPORTING THE RECOMMENDATIONS
BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS
QUALIFYING STATEMENTS
IMPLEMENTATION OF THE GUIDELINE
INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT
CATEGORIES
IDENTIFYING INFORMATION AND AVAILABILITY
DISCLAIMER

SCOPE

DISEASE/CONDITION(S)

- Hematologic and other malignancies
- Various genetic disorders

GUIDELINE CATEGORY

Management Treatment

CLINICAL SPECIALTY

Oncology Radiation Oncology Radiology

INTENDED USERS

Advanced Practice Nurses Allied Health Personnel Nurses Physician Assistants Physicians

GUIDELINE OBJECTIVE(S)

- To assist practitioners in providing effective and safe radiologic care for patients
- To describe principles of practice for total body irradiation in hematologic malignancies

TARGET POPULATION

Patients undergoing total body irradiation (TBI) for cytoreduction and immunosuppression

INTERVENTIONS AND PRACTICES CONSIDERED

- 1. Total body irradiation (TBI) including
 - Clinical evaluation
 - Obtaining informed consent
 - Treatment planning
 - Simulation of treatment
 - Dose calculations
 - Treatment delivery and treatment aids
- 2. Qualifications and responsibilities of personnel
- 3. Patient and personnel safety measures
- 4. Types of equipment needed
- 5. Documentation
- 6. Continuing medical education programs for medical staff
- 7. Quality control and improvement and patient education

MAJOR OUTCOMES CONSIDERED

Not stated

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Not stated

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

This guideline was revised collaboratively with the American College of Radiology (ACR) and the American Society for Therapeutic Radiology and Oncology (ASTRO).

Each practice guideline and technical standard, representing a policy statement by the American College of Radiology (ACR), has undergone a thorough consensus process in which it has been subjected to extensive review, requiring the approval of the Commission on Quality and Safety as well as the ACR Board of Chancellors, the ACR Council Steering Committee, and the ACR Council.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The guidelines are approved by the Commission on Quality and Safety as well as the American College of Radiology (ACR) Board of Chancellors, the ACR Council Steering Committee, and the ACR Council.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Fractionated total body irradiation (TBI) in conjunction with the use of chemotherapeutic agents has proven useful for cytoreduction and immunosuppression prior to bone marrow or peripheral blood stem cell transplantation for hematologic and other malignancies and for various genetic disorders. Unique features of TBI, rendering it a valuable component of transplant preparative regimens, in contrast to chemotherapy, include:

- 1. No sparing of "sanctuary" sites (e.g., testes)
- 2. Dose homogeneity regardless of blood supply
- 3. No known cross-resistance with other agents
- 4. No problems with excretion or detoxification
- 5. Ability to tailor the dose distribution by shielding specific organs or by "boosting" sites

Single fraction low dose TBI has recently emerged as an effective form of immunosuppression (with or without chemotherapy) prior to allogeneic stem cell transplantation in nonmyeloablative approaches.

The purposes of TBI are primarily to immunosuppress (in allogeneic transplants) and to cytoreduce (eradicate malignant cells or, occasionally, cell populations with genetic disorders).

It is essential that the complicated treatment and care of the patient receiving a transplant regimen containing TBI is well coordinated among the various services (medical oncology, radiation oncology, etc.) and caregivers (physicians, nurses, physicists, psychologists, dieticians, etc). Unlike most other treatment delivered by a radiation oncologist, fractionated TBI delivers results in myeloablation that is potentially lethal without intensive medical support and stem cell backup. Incorrectly delivered TBI may result in fatal toxicity as well. Thus, great care must be taken by the entire TBI team to assure the best possible multidisciplinary treatment plan with attention to all facets of TBI.

Although the techniques vary widely from institution to institution, certain basic principles apply, such as the achievement of dose homogeneity throughout the body, with the exception of shielded or boosted areas. The planning and performance of TBI is a team effort that requires close interaction and coordination among the radiation oncologist, the medical physicist, dosimetrists, nurses, and radiation therapists.

This guideline describes a quality assurance program for TBI and is supplementary to the <u>ACR Practice Guideline for Radiation Oncology (see National Guideline Clearinghouse summary)</u> and the <u>ACR Technical Standard for the Performance of Radiation Oncology Physics for External Beam Therapy.</u>

Process of Total Body Irradiation

The use of TBI is a complex process involving many trained personnel who carry out highly coordinated activities.

A. Clinical Evaluation

The initial evaluation should include a detailed history, including a review of issues that may impact upon treatment tolerance (previous radiotherapy to sensitive organs, factors affecting pulmonary, renal or hepatic function, and exposure to infectious agents); physical examination; review of all pertinent diagnostic and laboratory tests; and communication with the referring physician and other physicians involved in the patient's care in accordance with the <u>ACR Practice Guideline for Communication: Radiation Oncology</u>. Careful review of the applicable protocol for the particular disease being treated is essential since standardized institutional or cooperative group protocols are the norm for transplantation.

As with delivery of any chemotherapy or radiotherapy, policies and procedures should be in place to determine whether a female patient is pregnant before initiating any component of a transplant program, including TBI. If the patient is determined to be pregnant, alternative therapies in an effort to preserve the pregnancy versus termination of pregnancy and continuation with transplantation must be decided upon.

B. Informed Consent

Prior to simulation and treatment, informed consent must be obtained and documented and must be in compliance with applicable laws, regulations, or policies. This should include a detailed discussion of the benefits and potential tissue-specific acute and late toxicities of TBI, as well as the details of, rationale for, and alternatives to TBI.

C. Treatment Planning

Treatment planning for TBI requires detailed knowledge of the specific transplant program to be followed (either on or off of a clinical trial). Specific treatment parameters to be determined in advance of treatment include: field size, dose per fraction, dose rate, total dose, fractions per day, interval between fractions, if relevant, beam energy, geometry to achieve dose homogeneity, bolus or beam spoilers to increase skin dose, shielding and dose compensation requirements (e.g., lungs, kidneys), and boost specifications (e.g., testes). Patient thickness measurements should be obtained at the prescription point (often at the level of the umbilicus), and at other points of interest for possible dose calculations and homogeneity determinations such as head, neck, mid-mediastinum, mid-lung, pelvis, knee,

ankle, etc. Patient height is recorded in order to determine the appropriate source-to-patient distance to appropriately fit the patient within the beam with sufficient margin around the patient (>5 cm, usually).

D. Simulation of Treatment

For lung or other organ blocking, simulation or other treatment planning is generally done in the treatment position (i.e., if the patient is standing for TBI, the simulation should be done in the standing position if possible). If the planning session is performed in another position, positional differences in organ location should be taken into account, and the medical physicist should be consulted. Reference points for block placement at the time of treatment should be marked on the patient's body for reproducibility.

E. Calculations

Calculations are performed by the medical physicist or his or her designee to determine beam-on time to achieve the prescribed dose, dose homogeneity in the locations specified by the protocol, and doses at any other points of concern. A medical physicist or a dosimetrist who did not perform the initial computation shall independently check the calculation before the first fraction is delivered. In vivo dosimetry may aid in assessment of dose homogeneity. Every effort should be made to maintain dose inhomogeneity to within +/-10%.

F. Treatment Aids

Special TBI stands or tables are often used to aid in immobilization, placement of organ shields, and patient support and comfort.

G. Treatment Delivery

TBI containing myeloablative transplant programs typically utilize fractionated or hyperfractionated regimens (twice a day or three times a day) over several days in order to minimize both acute and chronic toxicities and to minimize overall treatment time. Prior to treatment, any shielding of normal organs should be checked with portal images. In the setting of single fraction lowdose TBI, where total doses are typically only 200 cGy, organ shielding is not utilized. Dosimetry should be checked against department protocols to verify dose delivery at the extended distances that are usually used for treatment. A medical physicist should be available during all treatments in case of questions regarding dosimetric details, equipment function, patient setup, etc. Treatments are carried out by the radiation therapist per the ACR Practice Guideline for Radiation Oncology.

A physician should be in close proximity to manage any problems related to treatment. Avoidance of medications that may cause orthostatic hypotension (such as phenothiazines), and the administration of intravenous (IV) fluids for hydration or transfusions for anemia may help to prevent syncope or near-syncopal episodes when the patient is treated in the standing position.

Qualifications and Responsibilities of Personnel

Application of this guideline should be in accordance with the <u>ACR Practice</u> Guideline for Radiation Oncology.

A. Radiation Oncologist

The radiation oncologist shall have had training in TBI procedures prior to embarking on any of these regimens.

The responsibilities of the radiation oncologist include:

- 1. Consultation and decision-making regarding the course of treatment.
- 2. Coordination of the patient's care with the transplantation service.
- 3. Participation in the treatment planning process (immobilization techniques, simulation, block design, prescription, etc.).
- 4. Review and verification of portal images.
- 5. Clinical assessment of the patient's tolerance during the treatment course.

B. Qualified Medical Physicist

The responsibilities of the Qualified Medical Physicist include:

- 1. Establishment and management of a quality assurance program for TBI performance.
- 2. Acting as a technical resource for planning of immobilization devices, dosimetry techniques, shielding, dose compensation devices, and bolusing methods.
- 3. Calibration of the external beam delivery system.
- 4. Direct supervision of dosimetry measurements and calculations for TBI delivery.

C. Dosimetrist

The responsibilities of the dosimetrist include:

- 1. Generation of the dose calculations for treatment.
- 2. Dosimetry measurements.

D. Radiation Therapist

The responsibilities of the radiation therapist include:

- 1. Setting up the patient in the treatment position, including using appropriate treatment devices.
- 2. Performance of imaging procedures to verify the setup and blocking, if any.
- 3. Treatment of the patient according to the prescription and plan provided.

- 4. Continuing monitoring and evaluation of the patient during the treatments.
- 5. Verification that the prescribed and calculated treatment distances match the utilized treatment distances.

E. Nurse

The responsibilities of the nurse may include:

- 1. Monitoring the patient's tolerance of the procedure to promote adequate supportive care.
- 2. Communicating any special precautions to the rest of the team regarding the care of immunosuppressed patients.

Equipment

High-energy photon beams are used for TBI, generally delivered by linear accelerators in the range of 4–18 MV or by a Co-60 unit. Additional equipment may include a fluoroscopy or computed tomography (CT) simulator, immobilization devices, equipment for the manufacture of shielding, computers for dose calculations, a beam spoiler, custom bolus, custom compensators, and dosimetry and calibration devices. A backup beam delivery system must be available in case of unanticipated machine failure.

Patient and Personnel Safety

- A. Safety measures should be in accordance with the <u>ACR Practice Guideline for</u> Radiation Oncology.
- B. Special Patient Protection Measures
 - 1. Charting systems for prescription; delineation of treatment parameters of the setup; including any position settings of the TBI stand; and treatment delivery record, including time of delivery for multiple treatments in a day.
 - 2. Physics program for calibration of the treatment machine, independent checking of dose calculations, and monitoring of dose delivery to the patient.
 - 3. Visual and audio contact with the patient during treatment.

Documentation

Reporting should be in accordance with the <u>ACR Practice Guideline for Communication: Radiation Oncology</u>.

Educational Program

Continuing medical education programs should include radiation oncologists, physicists, dosimetrists, nurses, and radiation therapists. The program should be in accordance with the <u>ACR Practice Guideline for Continuing Medical Education (CME)</u>.

Quality Control and Improvement, Safety, Infection Control, and Patient Education Concerns

See the "Description of the Implementation Strategy" field, below.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is not specifically stated for each recommendation.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate performance of total body irradiation to ensure accurate and safe treatment

POTENTIAL HARMS

- Potential toxicities of total body irradiation (TBI)
- Unlike most other treatment delivered by a radiation oncologist, fractionated TBI delivers results in myeloablation that is potentially lethal without intensive medical support and stem cell backup. Incorrectly delivered TBI may result in fatal toxicity as well.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- These guidelines are an educational tool designed to assist practitioners in providing appropriate radiologic care for patients. They are not inflexible rules or requirements of practice and are not intended, nor should they be used, to establish a legal standard of care. For these reasons and those set forth below, the American College of Radiology cautions against the use of these guidelines in litigation in which the clinical decisions of a practitioner are called into question.
- The ultimate judgment regarding the propriety of any specific procedure or course of action must be made by the physician or medical physicist in light of all the circumstances presented. Thus, an approach that differs from the guidelines, standing alone, does not necessarily imply that the approach was below the standard of care. To the contrary, a conscientious practitioner may responsibly adopt a course of action different from that set forth in the guidelines when, in the reasonable judgment of the practitioner, such course

- of action is indicated by the condition of the patient, limitations on available resources, or advances in knowledge or technology subsequent to publication of the guidelines. However, a practitioner who employs an approach substantially different from these guidelines is advised to document in the patient record information sufficient to explain the approach taken.
- The practice of medicine involves not only the science, but also the art of dealing with the prevention, diagnosis, alleviation, and treatment of disease. The variety and complexity of human conditions make it impossible to always reach the most appropriate diagnosis or to predict with certainty a particular response to treatment. Therefore, it should be recognized that adherence to these guidelines will not assure an accurate diagnosis or a successful outcome. All that should be expected is that the practitioner will follow a reasonable course of action based on current knowledge, available resources, and the needs of the patient to deliver effective and safe medical care. The sole purpose of these guidelines is to assist practitioners in achieving this objective.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

Quality Control and Improvement, Safety, Infection Control, and Patient Education Concerns

Policies and procedures related to quality, patient education, infection control, and safety should be developed and implemented in accordance with the ACR Policy on Quality Control Improvement, Safety, Infection Control, and Patient Education Concerns appearing elsewhere in the ACR Practice Guidelines and Technical Standards book.

The Medical Director of Radiation Oncology is responsible for the institution and ongoing supervision of continuing quality improvement (CQI) as described in the <u>ACR Practice Guideline for Radiation Oncology</u>. It is the responsibility of the director to identify problems, see that actions are taken, and evaluate the effectiveness of the actions.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better Living with Illness

IOM DOMAIN

Effectiveness Patient-centeredness Safety

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

American College of Radiology (ACR). ACR practice guideline for the performance of total body irradiation. Reston (VA): American College of Radiology (ACR); 2006. 5 p. [6 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2006

GUIDELINE DEVELOPER(S)

American College of Radiology - Medical Specialty Society

SOURCE(S) OF FUNDING

American College of Radiology

GUIDELINE COMMITTEE

Collaborative Subcommittee
Guidelines and Standards Committee

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Collaborative Subcommittee

American College of Radiology Committee Members: Rachel Rabinovitch, MD, Chair; Janice Kong-Ja Ryu, MD; Jeffrey Y. C. Wong, MD

American Society for Therapeutic Radiology and Oncology (ASTRO): Huan B. Giap, MD, PhD; Kenneth J. Russell, MD; Paula J. Schomberg, MD

Guidelines and Standards Committee

Committee Members: Laurie E. Gaspar, MD, MBA, Chair; E. Brian Butler, MD; Cassandra S. Foens, MD; John S. Kent, MS; Peter M. Mauch, MD; LaMar S. McGinnis, III, MD; Rachel Rabinovitch, MD; Seth A. Rosenthal, MD; Anthony H. Russell, MD; Oscar E. Streeter, Jr., MD; Vipul V. Thakkar, MD; Frank A. Vicini, MD; Gregory M. Videtic, MD, CM; Steven A. Leibel, MD, Commission Chair

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the American College of Radiology (ACR) Web site.

Print copies: Available from the American College of Radiology, 1891 Preston White Drive, Reston, VA 20191. Telephone: (703) 648-8900.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- ACR practice guidelines and technical standards purpose and intended use. Reston (VA): American College of Radiology; 1 p. Electronic copies: Available in Portable Document Format (PDF) from the <u>American College of Radiology</u> (ACR) Web site.
- The process for developing ACR practice guidelines and technical standards.
 Reston (VA): American College of Radiology; 1 p. Electronic copies: Available
 in Portable Document Format (PDF) from the <u>American College of Radiology</u>
 (ACR) Web site.

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI Institute on August 20, 2007. The information was verified by the guideline developer on August 23, 2007.

COPYRIGHT STATEMENT

Instructions for downloading, use, and reproduction of the American College of Radiology (ACR) Practice Guidelines & Technical Standards may be found on the <u>ACR Web site</u>.

DISCLAIMER

NGC DISCLAIMER

The National Guideline Clearinghouse™ (NGC) does not develop, produce, approve, or endorse the guidelines represented on this site.

All guidelines summarized by NGC and hosted on our site are produced under the auspices of medical specialty societies, relevant professional associations, public or private organizations, other government agencies, health care organizations or plans, and similar entities.

Guidelines represented on the NGC Web site are submitted by guideline developers, and are screened solely to determine that they meet the NGC Inclusion Criteria which may be found at http://www.quideline.gov/about/inclusion.aspx.

NGC, AHRQ, and its contractor ECRI Institute make no warranties concerning the content or clinical efficacy or effectiveness of the clinical practice guidelines and related materials represented on this site. Moreover, the views and opinions of developers or authors of guidelines represented on this site do not necessarily state or reflect those of NGC, AHRQ, or its contractor ECRI Institute, and inclusion or hosting of guidelines in NGC may not be used for advertising or commercial endorsement purposes.

Readers with questions regarding guideline content are directed to contact the guideline developer.

© 1998-2008 National Guideline Clearinghouse

Date Modified: 9/29/2008

